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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,587	11/29/2001	Sacha Adrianus Fokke Taco Van Hijum	BO43667-CIP	2951

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EXAMINER	
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ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/995,587	Van Hijum et al.
Examiner	**Art Unit**
Rebecca Prouty	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 3, 2002*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-9 and 11-23* is/are pending in the application.

4a) Of the above, claim(s) *1-9 and 11-14* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *15-23* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. *09/604,958*.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claim 10 has been canceled. Claims 1-9, 11-14 and new claims 15-23 are at issue and are present for examination.

Applicant's election with traverse of Group III, corresponding to new Claims 15-23 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that no burden of search exists for the coexamination of Groups III-V and VII. This is not found persuasive because the search required for each of Groups IV, V and VII is no coextensive with the search required for Group III. For example search of Group IV would require search of the subclass 514/54, search of Group V would require search of subclass 435/252.9 and search of Group VII would require search of subclass 424/78.01 all of which subclasses are unnecessary for a search of elected Group III. Applicants statement that separate classification has no evidence of propriety of the requirement of restriction is incorrect as separate classification is *prima facie* evidence of a serious additional burden of search on the examiner (see MPEP 803).

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-9 and 11-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking

claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Claim 23 is objected to because of the following informalities: "said protein has" in line 3 is grammatically awkward and in line 5, "sequence of" is misspelled "sequenco ef". It is suggested that line 3 be amended to recite "said protein having". Appropriate correction is required.

Claims 18, and 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 is unclear as to the scope of products intended to be recited. Is the claim limited to producing an inulin and/or a levan or does it encompass producing other fructo-oligosaccharides?

Claim 20 is confusing in the recitation "3,4-oxidation". Does this encompass oxidation at either the 3 or 4 position or require oxidation of both positions? Claim 20 is further confusing with regard to the scope of saccharides that are being modified. Can the modification be to any oligosaccharide or polysaccharide produced by the method of Claim 15 or only to one or more anhydrofructose unit(s) of a fructan with a degree of polymerization of at least 100?

Claims 21 and 22 are unclear in the recitation of "food grade vehicle" as it is not defined what this encompasses and this is not standard terminology in the art. For purposes of examination Claim 21 has been interpreted as adding one or more additional components suitable for ingestion by an animal to the fructan composition produced by the method of Claim 15 and Claim 22 has been interpreted as adding a *Lactobacillus* strain and optionally one or more additional components suitable for ingestion by an animal to the fructan composition produced by the method of Claim 15.

Claim 22 is indefinite in the recitation of "symbiotic composition" as this term is generally applied to a composition of two or more microorganisms capable of growth together, however the composition produced by the claimed method does not produce a composition of two or more microorganisms but instead a composition of a fructan and a microorganism. As such the meaning of the term "symbiotic" is unclear.

Claims 15, and 18-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are directed to methods of using a genus of fructosyltransferases. The specification teaches the structure of only two representative species of such proteins (i.e., SEQ ID NOS:1 and 11). Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of having fructosyltransferase activity. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 15, 16 and 18-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of using fructosyltransferases having at least 85% amino acid sequence identity to SEQ ID NOS:1 or 11, does not reasonably provide enablement for methods of using any fructosyltransferase comprising 15 amino acids of SEQ ID NOS:1 or 11. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 15, 16 and 18-23 are so broad as to encompass methods of using any fructosyltransferase comprising 15 amino acids of SEQ ID NOS:1 or 11. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of fructosyltransferase enzymes broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to 2 specific fructosyltransferases.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect

any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass methods of use of enormous numbers of modifications and fragments of the fructosyltransferases of SEQ ID NO:1 and 11 because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting fructosyltransferase activity; (B) the general tolerance of fructosyltransferases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any fructosyltransferase residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including methods of use of enormous numbers of modifications and fragments of the fructosyltransferases of SEQ ID NOS:1 and 11. The scope of the claims must bear a reasonable correlation with the scope of

enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of fructosyltransferases having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-20 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by van Geel-Schutten et al. (1999) or van Geel-Schutten et al. (1998).

Each of van Geel-Schutten et al. (1999) and van Geel-Schutten et al. (1998) teach the cultivation of *Lactobacillus reuteri* strain LB 121, and use this strain for the synthesis of fructan using enzymes found both intracellularly and extracellularly. As the strain cited in each of these references is identical to that used by applicants, the methods of van Geel-Schutten et al. (1999) and van Geel-Schutten et al. (1998) inherently use the enzymes of SEQ ID NO:1 and 11 and anticipate Claim 15-19 and 23. Furthermore, each of van Geel-Schutten et

al. (1999) and van Geel-Schutten et al. (1998) teach the further hydrolysis of the fructan produced and van Geel-Schutten et al. (1999) also teach the methylation of the fructan further anticipating Claim 20.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of van Geel-Schutten et al. (1999) and van Geel-Schutten et al. (1998).

van Geel-Schutten et al. (1999) and van Geel-Schutten et al. (1998) are discussed above. Each of these references further teach that extracellular polysaccharides such as those produced by the *Lactobacillus reuteri* strain LB 121 find use a food

thickeners and that lactic acid bacteria themselves often also contribute positively to the taste, smell or preservation of food products.

Therefore, it would have been obvious to one of ordinary skill in the art to combine the extracellular polysaccharides produced by either of van Geel-Schutten et al. (1999) and van Geel-Schutten et al. (1998) and optionally other lactic acid bacteria such as other *Lactobacillus* strains with additional components of such foods.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (703) 308-4000. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Rebecca Prouty
Primary Examiner
Art Unit 1652